UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE STEMLINE THERAPEUTICS, INC. SECURITIES LITIGATION	17 Civ. 832 (PAC) CLASS ACTION **OPINION & ORDER**

HONORABLE PAUL A. CROTTY, United States District Judge:

This is a securities case brought by buyers of stock in Stemline Therapeutics, Inc. ("Stemline"), which develops a highly sophisticated and complicated drug for the treatment of an otherwise fatal blood cancer. The buyers contend they were misled by Stemline's claimed ability to remediate certain fatal side effects of its drug.

Lead Plaintiffs Adam Ludlow, Daljit Singh, and Kenneth Walsh, and Representative Plaintiff Marion Beeler ("Plaintiffs") bring this consolidated class action[1] against Stemline, its officers and directors, Ivan Bergstein, Ron Bentsur, Eric L. Dobmeier, Alan Forman, David Gionco, Kenneth Zuerblis ("Individual Defendants"), and its underwriter, Jefferies LLC ("Jefferies"), alleging violations of: Sections 10(b) and 20(a) of the Exchange Act (Counts I, II); and Sections 11, 12(a)(2), and 15 of the Securities Act (Counts III–V). Plaintiffs, who allegedly purchased Stemline securities (1) pursuant and/or traceable to Stemline's secondary public offering on or about January 20, 2017 ("Offering") and/or (2) on the open market between January 20, 2017 and February 1, 2017 ("Class Period"), claim that they suffered injury from Stemline's misleading statements in the Offering's prospectus concerning its ability to remediate side effects of the drug under development.

[1] Initially, four separate class action complaints were filed: Case Nos. 17 Civ. 00832; 17 Civ. 00853; 17 Civ. 00940; 17 Civ. 01003. They were subsequently consolidated under the instant docket 17 Civ. 832 (PAC). *See* ECF 26.

Stemline, Individual Defendants, and Jefferies move to dismiss the Amended Complaint. ECF 42, 45. For reasons set forth below, the motion to dismiss is **GRANTED**.

BACKGROUND

I. Development of SL-401

Stemline is a clinical stage biopharmaceutical company that acquires, develops, and commercializes proprietary oncology therapeutics. Its leading drug candidate and key value driver is SL-401. Amended Complaint ("AC"), ¶¶14, 30. SL-401 treats certain rare, blood-related and otherwise fatal cancers, including blastic plasmacytoid dendritic cell neoplasm ("BPDCN") and acute myeloid leukemia ("AML"). *Id.* ¶¶2, 30.

Stemline began its clinical development program for SL-401 in July 2014. Upon achieving initial success, it broadened the trial into a pivotal trial with a plan to enroll at least 60 patients. *Id.* ¶36. The pivotal trial opened with a lead-in phase to evaluate the dosage and safety. *Id.* ¶¶25, 36. The lead-in phase was followed by an expansion phase to determine whether the SL-401 drug treatment was efficacious against the blood cancer. *Id.* ¶¶25, 42. The lead-in phase was completed on June 30, 2015, and the expansion phase began thereafter, with the goal of submitting a marketing application to the Food and Drug Administration ("FDA") during the second half of 2017. *Id.* ¶¶37, 42.

On December 7, 2015, Stemline reported on the clinical data of 29 patients treated with SL-401 during the lead-in phase and the on-going expansion phase. *Id.* ¶¶37, 39, 40; ECF 43-6 at 9. Three of the treated patients had contracted severe capillary leak syndrome ("CLS")[2], a now-known side effect of SL-401, two of whom had died from it and one of whom had experienced a

[2] CLS occurs when a thin layer of endothelial cells that line capillary walls separates, allowing fluid from the circulatory system to leak into the interstitial space. AC ¶38. CLS is a devastating and life threatening side effect. *Id.* ¶40. While it is the kind of life threatening side effect that could derail approval by the Food and Drug Administration ("FDA"), *id.* ¶41, it is uncontested that the FDA took no such action and the trials continued. It appears that the FDA encouraged the pursuit of clinical trials by granting Stemline Breakthrough Therapy Designation status.

life-threatening emergency. AC ¶40. Stemline implemented a safety and dosage protocol to minimize the risk of CLS. The trial continued and no additional case of severe CLS was observed until January 2017. *Id.* ¶¶41, 48.

As the expansion phase continued, in August 2016, the FDA granted the Breakthrough Therapy Designation ("BTD") status to SL-401 because the drug demonstrated substantial improvements over existing therapies: during the BPDCN trial, it demonstrated high overall response rates, with multiple complete responses. *Id.* ¶¶29, 35, 45. Notably, the FDA granted the BTD status despite the fact that the side effect of SL-401 had caused two deaths and one life-threatening emergency. *See id.* ¶¶40, 45. The BTD status provided for additional FDA guidance and a higher priority in the FDA's review and approval process. *Id.* ¶46.

On January 6, 2017, Stemline announced that it had entered into an agreement with the FDA on the registration pathway of SL-401 for the treatment of BPDCN, and would be enrolling an additional cohort of BPDCN patients in the ongoing pivotal trial to support the filing of a Biologics License Application for full approval of SL-401. *Id.* ¶47.

II. Safety Measure Failure

On or about January 14, 2017, one BPDCN patient enrolled in the pivotal trial developed a serious side effect, after receiving two of the five treatment cycles of SL-401 that began on January 13, 2017. In accordance with the revised safety and dosage protocol, doctors ceased administering SL-401 to the patient. *Id.* ¶¶48, 73. On January 17, 2017, the patient's family reported that the patient had been "diagnosed with Capillary Leak Syndrome, which [was] a known side effect of SL-401." *Id.* ¶74. On January 18, 2017, the patient died. *Id.* ¶48. Stemline learned of the patient's death on the same day. *Id.* ¶49.

III. Secondary Public Offering and Offering Documents

On January 19, 2017, the day after the patient's death, Stemline announced the Offering of its common stock to fund the potential commercialization of SL-401. *Id.* ¶50. On January 20, 2017, Stemline filed the offering documents (Form 424B5), including the Prospectus, with the U.S. Securities and Exchange Commission ("SEC") and, on the same day, offered 4.5 million shares of Stemline common stock at $10.00 per share, totaling $45 million. *Id.* ¶¶51, 52.

The Offering's Prospectus detailed SL-401's prior and then-current trials, including the Pivotal Trial. *Id.* ¶53. The Prospectus provided facts and assessments concerning prior clinical trials by incorporating prior SEC filings by reference. *See id.* ¶¶55–64. The Prospectus also stated that "SL-401's safety profile has continued to remain predictable and manageable over increasing treatment duration, drug exposure, and patient experience," *id.* ¶65, and "favorable clinical data" have been observed as of the date of the offering documents, *id.* ¶66. The Prospectus did not disclose the patient's death that Stemline had learned on January 18, 2017. *Id.* ¶53.

IV. Public Disclosure of Patient's Death

On February 2, 2017, *The Street* published an article revealing that on January 17, 2017, a BPDCN patient had been diagnosed with CLS and had died the next day. *Id.* ¶67. The article included several unfounded commentaries on SL-401 and the FDA approval process. For example, the article stated that "a cancer patient in a clinical trial died from a severe side effect, a type of low blood pressure tied to the company's drug SL-401" and "[SL-401] is also now tied to three patient deaths," when the cause of the patient's death had not yet been determined. ECF 43-13 at 1, 2. The article also stated that "[t]he inability to control serious, potentially fatal, side effects can derail otherwise highly effective experimental therapies, even cancer drugs," when the FDA actually granted the BTD status to SL-401 with the knowledge that it had caused two deaths and one life-threatening condition. *Id.* at 2; AC ¶¶40, 45.

Later the same day, Stemline issued a press release, confirming that a BPDCN patient had developed CLS and had died, and that it had learned of the death on January 18, 2017. *Id.* ¶68. Stemline, however, clarified that "[t]he cause of the patient's death [had] not yet been determined." *Id.* That day, Stemline's stock price fell by $4.15, from $9.75 to $5.60, or approximately 42.5%. *Id.* ¶69; ECF 43-16 ("Stock Price Chart")[3]. A deluge of litigation immediately followed. *See supra*, n.1. The stock price rebounded swiftly, however, and by March 10, 2017, it climbed back to the level before the disclosure of the patient's death. *See* Stock Price Chart.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* When considering a motion to dismiss pursuant to the Federal Rule of Civil Procedure 12(b)(6), the Court "must accept as true all of the factual allegations contained in the complaint," and construe the complaint in the light most favorable to the plaintiff. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007).

Allegations of securities fraud must meet the heightened pleading standards of the Federal Rule Civil Procedure 9(b), *see ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009) ("ECA"); and of the Private Securities Litigation Reform Act ("PSLRA"), which requires, with respect to each act or omission, that the complaint "state[s] with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," 15 U.S.C. § 78u-4(b)(2).

[3] The Court takes judicial notice of the Stock Price Chart. *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 167 n.8 (2d Cir. 2000) (The Court "may take judicial notice of well-publicized stock prices....").

DISCUSSION

Plaintiffs claim that the Offering's Prospectus misstated and omitted material facts concerning a new occurrence of severe CLS in SL-401's Pivotal Trial. The alleged misrepresentations and omissions are said to have artificially inflated the price of Stemline securities, both at the Offering and throughout the 13-day Class Period; and they purportedly caused injury to Plaintiffs when the underlying truth was revealed on February 2, 2017, causing a significant drop in the stock price. AC ¶¶70, 71.

Plaintiffs assert five causes of action: (1) Count I under Section 10(b) of the Exchange Act and Rule 10b–5 against all Defendants; (2) Count II under Section 20(a) of the Exchange Act against Individual Defendants; (3) Count III under Section 11 of the Securities Act against all Defendants; (4) Count IV under Section 15 of the Securities Act against Individual Defendants; and (5) Count V under Section 12(a)(2) of the Securities Act against Individual Defendants and Jefferies. *See generally* AC. None of the asserted causes of action is adequately pleaded because Plaintiffs have failed to allege sufficient facts to show that Defendants made any actionable misstatements or omissions. None of the causes of action survives the motion to dismiss.

I. The Exchange Act

A. Count I: Claims under Section 10(b) and Rule 10b-5 against All Defendants

Section 10(b) of the Exchange Act prohibits any person from using or employing "any manipulative or deceptive device or contrivance in contravention" of SEC rules. 15 U.S.C. § 78j(b). Rule 10b-5, promulgated under Section 10(b), prohibits "any device, scheme, or artifice to defraud" and "any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made . . . not misleading . . . ." 17 C.F.R. § 240.10b-5.

To bring a successful claim under Section 10(b) of the Exchange Act and Rule 10b-5, a plaintiff must allege sufficient facts to establish that a defendant "(1) made misstatements or

omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which plaintiffs relied; and (5) that plaintiffs' reliance was the proximate cause of their injury." *In re Puda Coal Sec. Inc., Litig.*, 30 F. Supp. 3d 261, 265–66 (S.D.N.Y. 2014) (quoting *In re IBM Corp. Sec. Litig.*, 163 F.3d 102, 106 (2d Cir. 1998)). Plaintiffs have, however, failed to allege sufficient facts to establish that Defendants made any actionable misstatements or omissions. Plaintiffs contend that Defendants made two types of misleading statements about SL-401 and its clinical trials in the Prospectus: (1) statements incorporated by reference to historical SEC filings; and (2) affirmative statements. *See* ECF 43-12 ("Prospectus"), at S-1–S-4; 4. The Court disagrees: these statements were neither false nor misleading, as discussed below.

i. Statements Incorporated by Reference

1. Statements incorporated by reference were not misstatements.

The incorporated statements were not misstatements because they were not false when made. *See In re Magnum Hunter Res. Corp. Sec. Litig.*, 26 F. Supp. 3d 278, 290 (S.D.N.Y. 2014) ("An allegedly material misstatement must have been false at the time that it was made"). The Court has no reason to doubt that the incorporated statements were true at the time the incorporated documents were filed with the SEC. Nor does it have any reason to doubt that they were true at the time the Prospectus was filed with the SEC: both the Prospectus and the incorporated documents had explicit disclaimers providing ample warnings that the incorporated statements represented facts that had existed at the time the incorporated documents were filed with the SEC.[4]

[4] *See, e.g.*, Prospectus at Table of Contents ("You should assume that the information appearing in … the documents incorporated by reference in this prospectus supplement and the accompanying prospectus … is *accurate only as of the date of those respective documents*. Our business, financial condition, results of operations and prospects may have changed since those dates.") (emphasis added); *Id.* at 4 ("You should assume that the information appearing in this prospectus, as well as information we previously filed with the SEC and have incorporated by reference, is accurate as of the date on the front cover of this prospectus only, or *when such document was filed with the SEC*. Our business, financial condition, results of operations and prospects may have changed since the relevant date") (emphasis added).

Plaintiffs contend that by incorporating its 2015 10-K form into the Prospectus, "Stemline falsely stated that enhanced safety and dosage protocols it had developed to combat a severe, life-threatening side-effect of SL-401 … had eliminated any further CLS occurrence." AC ¶2. *See also id.* ¶¶3, 4; Opp'n Mem. at 1, 2, 9, 10, 13, 14, 26. This is a complete mischaracterization. Stemline never claimed to have eliminated the CLS side effect. The incorporated 2015 10-K form merely stated that its dosage guideline was "designed to minimize the risk of severe capillary leak syndrome (CLS)" and that "[s]ince implementation of these measures, severe CLS [had] not been observed at doses up to 12 ug/kg/day." *Id.* ¶55. Plaintiffs cannot make up statements and then attribute them to defendants in order to support a Section 10(b) claim.

2. Statements incorporated by reference were not misleading.

Plaintiffs contend that the incorporated statements were misleading because Stemline did not disclose the new occurrence of severe CLS. *See* Opp'n Mem. at 13–15. The incorporated statements, which revealed data from an earlier phase of the clinical trial, created "a duty to tell the whole truth" about the remainder of the clinical trial, including the inopportune occurrence of severe CLS. *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016). The purported failure to do so rendered the incorporated statements misleading. *See* Opp'n Mem. at 13–15.

Plaintiffs' argument is not convincing. Stemline periodically reported on its clinical trial results. For example, it reported in December 2015 on the earlier results for 29 enrolled patients: three had contracted the expected CLS, two of whom had died. The report on deaths was not contemporaneous. AC ¶¶37, 39, 40; ECF 43-6 at 9. The case law is clear that Stemline did not have a general duty to disclose any additional isolated occurrence of severe CLS. *See In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 332 (S.D.N.Y. 2014) ("Pharmaceutical companies need not disclose 'isolated reports of illnesses suffered by users.'") (quoting *In re Carter–Wallace, Inc.*

Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998)). Stemline's silence could not have been misleading when there was no duty to disclose. *Basic Inc. v. Levinson*, 485 U.S. 224, 239, n.17 (1988).

While the incorporated statements could have created a duty to disclose the new occurrence of severe CLS, they could have done so only if they would have led a reasonable investor to believe that the historical data in the incorporated statements were somehow representative or predictive of SL-401's performance as of the Offering date. *See In re Centerline Holdings Co. Sec. Litig.*, 613 F. Supp. 2d 394, 398 (S.D.N.Y. 2009). Nothing supports such an inference here. The Prospectus and the incorporated documents were very clear that the data in the incorporated documents were historical only. *See supra*, n.4. In view of ample disclaimers, a reasonable investor could not have deemed the incorporated statements to be representative of the drug's performance as of the Offering date. Thus, the incorporated statements could not have created any duty to disclose the new occurrence of severe CLS, and the purported failure to disclose it could not have rendered the incorporated statements misleading.

ii. Affirmative Statements in Prospectus

While Plaintiffs' primary argument for their Section 10(b) claim is that Stemline falsely claimed it had eliminated the risk of CLS, (*see* AC ¶¶2–4; Opp'n Mem. at 1, 2, 9, 10, 13, 14, 26), it is clear that Stemline never claimed that it had eliminated CLS risks; "elimination" is a fabrication by Plaintiffs. Plaintiffs also contend that following affirmative statements in the Prospectus were misleading:

(1) "SL-401's safety profile has continued to remain predictable and manageable over increasing treatment duration, drug exposure, and patient experience." AC ¶65.

(2) "[F]avorable clinical data [were] observed to date with SL-401." *Id.* ¶66.

Stemline claims these statements were not misleading because they reflected opinions; and were not rendered misleading by a single adverse event. Stemline Mem. at 15–16. The Court agrees.

The concerned statements—"predictable and manageable" and "favorable clinical data"—are expressions of opinion. Expressions of opinion may be actionable "if a registration statement omits material facts about the issuer's … knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1329 (2015). It is uncontested that the Prospectus was filed after the patient's death on January 18, 2017. The question is whether the patient's death "conflict[ed] with what a reasonable investor would [have taken] from" opinion statements in the Prospectus: "predictable and manageable" and "favorable clinical data."

The question must be answered in the negative. To a reasonable investor, a recurrence of a known side effect, CLS, would not have been unexpected. CLS was a known fatal side effect of SL-401. It had caused two deaths in the past, and the deaths were not disclosed contemporaneously, but only later. AC ¶¶37, 39, 40. An additional case of severe CLS occurring in an on-going trial would not have been in "conflict with what a reasonable investor would [have taken] from" the concerned opinion statements. *Omnicare*, 135 S. Ct. at 1329. A reasonable investor "understand[s] that opinions sometimes rest on a weighing of competing facts," and "does not expect that *every* fact known to an issuer supports its opinion statement." *Id.* *See also Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) ("[A] statement of opinion is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way."). The concerned statements are not actionable.

For these reasons, Plaintiffs have failed to plead that Stemline made misstatements or omissions actionable under Section 10(b) of the Exchange Act. The Court draws the same conclusion with respect to Individual Defendants and Jefferies. Plaintiffs have failed to plead that Individual Defendants and Jefferies made actionable misstatements or omissions, or that any

actionable misstatements or omissions could be attributed to Individual Defendants and Jefferies. *In re Fannie Mae 2008 Sec. Litig.*, 891 F.Supp.2d 458, 473 (S.D.N.Y. 2012), *aff'd*, 525 Fed. Appx. 16 (2d Cir. 2013). Accordingly, Plaintiffs' Section 10(b) claim fails as a matter of law. The motion to dismiss the Section 10(b) claim is granted.

B. Count II: Claim under Section 20(a) against Individual Defendants

Plaintiffs allege control person liability under Section 20(a) of the Exchange Act against Individual Defendants. *See* 15 U.S.C. § 78t(a); AC ¶¶105–108. As discussed above, Plaintiffs have failed to plead a primary violation by Stemline. Plaintiffs' control person liability claim fails as a matter of law. *In re Alstom SA*, 406 F.Supp.2d 433, 486 (S.D.N.Y. 2005). The motion to dismiss the Section 20(a) claim is granted.

II. The Securities Act

A. Counts III and V: Claims under Sections 11 and 12(a)(2) of the Securities Act

Sections 11 and 12(a)(2) of the Securities Act create liability for material misrepresentations or omissions in connection with a registered security offering. *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 367 (S.D.N.Y. 2011). "Section 11 of the Securities Act prohibits materially misleading statements or omissions in registration statements filed with the SEC." *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 358 (2d Cir. 2010). "Section 12(a)(2) provides similar redress where the securities at issue were sold using prospectuses or oral communications that contain material misstatements or omissions." *Id.*

Plaintiffs have failed to state viable claims under Sections 11 and 12(a)(2) because, as discussed above, they have not pleaded sufficient facts to establish that any defendant made any material misrepresentations or omissions in connection with a registered security offering. *See supra* at 7–10. The motion to dismiss the claims under Sections 11 and 12(a)(2) is granted.

B. Count IV: Claim under Section 15 of the Securities Act

Section 15 "creates liability for individuals or entities that 'control any person liable' under section 11 or 12;" thus, a Section 15 claim requires a plaintiff to establish "primary liability" under Section 11 or 12. *In re Morgan Stanley*, 592 F.3d at 358. As discussed above, Plaintiffs have not pleaded sufficient facts to support primary liability under Sections 11 and 12. *See supra* at 11. The motion to dismiss the claim under Section 15 is granted.

CONCLUSION

For the foregoing reasons, the motion to dismiss the Amended Complaint is granted. All claims shall be dismissed with prejudice unless Plaintiffs moves for leave to amend the Amended Complaint in a manner consistent with Federal Rule of Civil Procedure § 15 within thirty days from the entry of this order.

The Clerk of the Court is directed to close the pending motions at ECF 42 and 45.

Dated: New York, New York
March 15, 2018

SO ORDERED

PAUL A. CROTTY
United States District Judge